

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE PFIZER INC. SECURITIES LITIGATION

No. 04-cv-9866 (LTS) (DFE)

**DECLARATION OF GREGORY A. MARKEL
IN SUPPORT OF DEFENDANTS' MOTION
TO EXCLUDE CERTAIN PLAINTIFFS' EXPERTS'
OPINIONS REGARDING CELEBREX AND BEXTRA**

GREGORY A. MARKEL, under penalty of perjury, declares as follows:

A. I am a member of the Bar of the State of New York and of the firm Cadwalader, Wickersham & Taft LLP, counsel for Defendants Pfizer Inc. (Pfizer), Dr. Henry A. McKinnell, Dr. John L. LaMattina, Karen L. Katen, Dr. Joseph M. Fezcko and Dr. Gail Cawkwell (collectively, "Defendants"). I submit this declaration in support of Defendants' Motion to Exclude Certain Plaintiffs' Experts' Opinions Regarding Celebrex and Bextra.

B. Attached hereto as Exhibits 1 – 161 are true and correct copies of the following documents:

1. Furberg, Curt D., Expert Report in the action captioned *In re Pfizer Inc. Securities Litigation*, dated March 6, 2009.
2. Kronmal, Richard A., Expert Report in the action caption *In re Pfizer Inc. Securities Litigation*, 2009.
3. Bennett, Joel S., M.D., Deposition Transcript in the action captioned *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, dated June 11-12, 2007.
4. Excerpts from Lawrence M. Friedman, Curt D. Furberg, and David L. DeMets, *Fundamentals of Clinical Trials*, 2 (3d ed. 1998).
5. Excerpts from Bengt D. Furberg & Curt D. Furberg, *Evaluating Clinical Research: All That Glitters Is Not Gold*, 11-12 (2d. ed. 2007).
6. Furberg, Curt D., Deposition Transcript in the action captioned *Valenzuela v. Warner-Lambert Co.*, dated July 31, 2002.
7. Furberg, Curt D., Deposition Transcript in the action captioned *Haslam v. Pfizer Inc.*, dated March 13-14, April 16, 2008.
8. Furberg, Curt D., Deposition Transcript in the action captioned *In re Pfizer Inc. Securities Litigation*, dated May 28-29, 2009, July 11, 2009.
9. Bennett, Joel S., Expert Report in the action captioned *In re Pfizer Inc. Securities Litigation*, dated March 6, 2009.
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11. Antiplatelet Trialist Collaboration, *Collaborative overview of randomised trials of antiplatelet therapy--I: Prevention of death, myocardial infarction, and stroke by prolonged antiplatelet therapy in various categories of patients. Antiplatelet Trialists' Collaboration*. BRIT. MED. J., 1994;308:81-106.
12. Kronmal, Richard A., Deposition Transcript in the action captioned *In re Pfizer Inc. Securities Litigation*, dated June 3-4, 2009.
13. Madigan, David, Deposition Transcript in the action captioned *In re Pfizer Inc. Securities Litigation*, dated June 11, 2009.
14. Furberg, Curt D., *Class effects and evidence-based medicine*. CLIN. CARDIOL. 2000;23;7 Suppl. 4:IV15-19.
15. Furberg, Curt D., *To whom do the research findings apply?* HEART 2002; 87:570-74.
16. Furberg, Curt D., et al., *Are drugs within a class interchangeable?* LANCET 1999;354:1202-04.
17. Furberg, POSTGRADUATE MEDICINE: A QUARTER-CENTURY OF BETA BLOCKADE (1988).
18. Jewell, Nicholas P., Deposition Transcript in the action captioned *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, dated June 21-22, 2007.
19. Jewell, Nicholas P., Deposition Transcript in the action captioned *In re Pfizer Inc. Securities Litigation*, dated June 17, 2009.
20. Furberg et al., *Parecoxib, valdecoxib, and cardiovascular risk*. CIRCULATION 2005;111:249.
21. Celebrex Label, Dec. 2008.
22. Singh & Ramey, *NSAID Induced Gastrointestinal Complications: The ARAMIS Perspective – 1997*. J. RHEUM. 1998;25(Supp. 51):8-16.
23. Transcript of the Joint Meeting of the FDA Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee, dated Feb. 16-18, 2005.
24. Celebrex Initial Approved Label, January 5, 1999.
25. Excerpts from the Celecoxib Integrated Summary of Safety Information, dated June 5, 1998.

26. James Witter, *Celebrex Medical Officer Review*, NDA No. 20-998, dated July 8, 1998.
27. Bombardier et al., *Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis*, N ENGL. J. MED., 2000;343:1520-28.
28. Pfizer Inc.'s Advisory Committee Briefing Document: *Celecoxib and Valdecoxib Cardiovascular Safety*, dated January 12, 2005.
29. Bresalier et al., *Cardiovascular events associated with rofecoxib in a colorectal adenoma chemoprevention trial*. N. ENGL. J. MED. 2005;352-63.
30. Celebrex Label, dated June 2002.
31. Vioxx Label, dated April 2002.
32. Graham, David J., Memorandum to Paul Seligman, "Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients Treated With COX-2 Selective and Non-Selective NSAIDs, dated Sept. 30, 2004.
33. Graham, David J., et al., *Risk of acute myocardial infarction and sudden cardiac death in patients treated with cyclo-oxygenase 2 selective and non-selective non-steroidal anti-inflammatory drugs: nested case-control study*. LANCET 2005;365:475-81.
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Erratum in: Am J Ther 2001 May-Jun;8(3):220.
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50. FDA Statement on the Halting of a Clinical Trial of the Cox-2 Inhibitor Celebrex, dated Dec. 17, 2004.
51. Memo from Monica Bertagnolli to Pfizer re: APC Trial Cardiovascular Safety Review, Oct. 15, 2004.
52. National Institutes of Health Press Release, *Use of Non-Steroidal Anti-Inflammatory Drugs Suspended in Large Alzheimer's Disease Prevention Trial*, dated Dec. 20, 2004.
53. Arber et al., *Celecoxib for the Prevention of Colorectal Adenomatous Polyps*, N. ENGL. J. MED. 2006;355:885-95.
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66. Weintraub, William, M.D., Expert Report in the action captioned *In re Pfizer Inc. Securities Litigation*, dated April 17, 2009.
67. Transcript of Proceedings, dated October 9, 2007, in the action captioned *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*.
68. Kronmal, Richard A. Ph.D., Excerpts of Deposition Transcript in the action captioned *McFarland v. Merck & Co., Inc.*, dated June 7, 2006.
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70. Cleveland Clinic Launches Large-Scale Global Trial to Examine Cardiovascular Safety of Popular Pain Relievers, dated December 13, 2005.
71. Furberg, Curt D., Expert Report in the action captioned *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, dated January 24, 2008.
72. Furberg, Curt D., Deposition Transcript in the action captioned *In re Rezulin Products Liability Litigation*, dated November 22, 2002.
73. Antman et al., *Use of Nonsteroidal Antiinflammatory Drugs. An Update for Clinicians. A Scientific Statement From the American Heart Association*. CIRCULATION 2007;115:1634-42.
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77. Excerpts from the Valdecoxib Integrated Summary of Safety, dated December 2000.

78. Letter from Jonca Bull of the FDA to Peter East of G.D. Searle & Co. re: approval for Bextra, dated Nov. 16, 2001.
79. Dear Healthcare Professional Letter, dated Sept. 2002, regarding Bextra.
80. Parecoxib sodium New Drug Application letter from Peter East to Jonca Bull, dated Sept. 11, 2000.
81. FDA Non-Approvable Letter from Jonca Bull to Peter East for parecoxib sodium, dated July 12, 2001.
82. Ott et al., *Efficacy and Safety of the Cyclooxygenase-2 Inhibitors Parecoxib and Valdecoxib in Patients Undergoing Coronary Artery Bypass Surgery*. J. THORAC. CARDIOVASC. SURG. 2003; 125:1481-92.
83. Witter, Dr. James, Presentation entitled *COX-2 CV Safety Valdecoxib/Parecoxib*, dated Feb. 16, 2005.
84. Johnson, Kent, Valdecoxib Medical Officer Review, dated November 7, 2001.
85. Letter From Peter East of Pharmacia to Jonca Bull of FDA regarding valdecoxib NDA, dated Oct. 17, 2001.
86. Email from Peter East to numerous recipients enclosing summary of Oct. 24, 2001 teleconference with FDA.
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89. Mar. 17, 2004 Submission to FDA, Pare IND 52613 00000473, 00000482.
90. Nussmeier et al., *Safety and Efficacy of Cyclooxygenase-2 Inhibitors Parecoxib and Valdecoxib after Noncardiac Surgery*. ANESTHESIOLOGY 2006;104:518-28.
91. Solomon D. et al., *Cardiovascular Outcomes in New Users of Coxibs and Nonsteroidal Antiinflammatory Drugs: High Risk Subgroups and Time Course of Risk*. ARTHR. RHEUM. 2006; 54:1378-89.
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93. Chen et al., *Do selective COX-2 inhibitors increase the risk of cerebrovascular events? A meta-analysis of randomized controlled trials.* J. CLIN. PHARM. THER. 2006; 31:565-76.
94. Chen et al., *Risk of myocardial infarction associated with selective COX-2 inhibitors: Meta-analysis of randomised controlled trials.* PHARMACOEPIDEMIOL. DRUG SAF. 2007; 16:762-72.
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97. Madigan, David, Ph.D., *Celebrex and Cardiovascular Risk*, Expert Report in the action captioned *In re Pfizer Inc. Securities Litigation*, dated March 12, 2009.
98. Madigan, David Ph.D., Expert Report in the action captioned *Grutka v. Pfizer Inc.*, dated August 22, 2008.
99. Madigan, David Ph.D., Deposition Transcript in the action captioned *Grutka v. Pfizer Inc.*, dated September 3-4, 2008.
100. Madigan, David Ph.D., *Vioxx and Cardiovascular Risk*, Expert Report, dated October 8, 2007.
101. Sever, et al., *Prevention of coronary and stroke events with atorvastatin in hypertensive patients who have average or lower-than-average cholesterol concentrations, in the Anglo-Scandinavian Cardiac Outcomes Trial--Lipid Lowering Arm (ASCOT-LLA): a multicentre randomised controlled trial.* LANCET 2003;361:1149-1158.
102. Jewell, Nicholas P., Rebuttal Expert Report, *In re Pfizer Inc. Securities Litigation*, dated April 17, 2009.
103. Letter from Geoffrey C. Jarvis to Gregory A. Markel and Jason M. Halper, dated July 6, 2009, including exhibits.
104. Furberg, Curt D., Deposition Transcript in the action captioned *Rushton v. Bayer Corporation* (Baycol), dated December 23, 2003.
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107. Zosia Chustecka, *Experts Condemn Furberg's Meta-Analysis Showing Calcium Channel Marketers to be Inferior*, HEARTWIRE, Sept. 1, 2000.
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111. Furberg, Curt D., Expert Report in the action captioned *In re Gadolinium-based Contrast Agents Liability Litigation*, dated June 11, 2009.
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113. Furberg, Curt D., Expert Report in the action captioned *In re Neurontin Sales Marketing and Products Liability Litigation*, dated December 11, 2008.
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116. Alonso-Zaldivar, Ricardo *FDA to Institute Safety Board*, L.A. TIMES, Feb. 16, 2005.
117. Rubin, Rita *Painkillers Hang in the Balance*, USA TODAY, Feb. 10, 2005.
118. Mundell, E.J. *Bextra Data Suggests All Cox-2 Drugs Pose Heart Risks*, HEALTH DAY, Jan. 18, 2005.
119. Henderson, Diedtra *Calls Are Mounting for Revamp of FDA*, BOSTON GLOBE, Dec. 25, 2004.
120. Fax from Paul Z. Balcer, Regulatory Health Project Manager to Kevin Phelan of Pfizer, dated March 3, 2005.

121. Email from Curt Furberg to Brian Harvey, dated Aug. 17, 2005, attaching letter from Curt Furberg to Brian Harvey, Acting Director of CDER's Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products, dated June 17, 2005.
122. Letter from Curt Furberg to Bob Rappaport, Director of CDER's Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products, dated Sept. 27, 2005.
123. Rita Rubin, *Another Drug for Pain off Market; Risk vs. Benefit for Bextra Cited*, USA TODAY, Apr., 8, 2005.
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128. Massie, Barry M. M.D., Expert Report in the action captioned *In re Pfizer Inc. Securities Litigation*, April 17, 2009.
129. Heckbert et al., *Beta2-adrenergic receptor polymorphisms and risk of incident cardiovascular events in the elderly*. CIRCULATION. 2003;107:2021-24.
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161. Baruch, Lawrence, M.D., Deposition Transcript in the action captioned *In re Pfizer Inc. Securities Litigation*, dated July 2, 2009.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: New York, New York
July 17, 2009



Gregory A. Markel

**DUE TO THE VOLUMINOUS NATURE OF THE EXHIBITS ATTACHED TO
THE MARKEL DECLARATION, DEFENDANTS REQUESTED AND
RECEIVED PERMISSION FROM THE COURT TO FILE THESE EXHIBITS IN
HARD COPY RATHER THAN VIA ECF. CERTAIN OF THESE EXHIBITS
WILL BE FILED UNDER SEAL.**